



State of California—Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

Instructions for Applying for a California Clinical Laboratory License

If you are applying for a CLIA Certificate of Compliance or a Certificate of Accreditation for the performance of moderate or high complexity testing, you must also apply for a California clinical laboratory license.

If you are applying for a CLIA Certificate of Waiver or Certificate for Provider Performed Microscopy Procedures (PPMP), you must apply for a state registration, not a state license. See separate instructions for applying for a state registration.

California Clinical Laboratory License Fee and Required Documents:

- **License fee** payable to the State of California Department of Health Services. The current fee is **\$978**, non-refundable and is subject to change with each fiscal year.
- Federal CLIA program will bill you separately for the CLIA certification fees.

State forms to complete:

- **LAB 144** – Application for Clinical Laboratory License
- **LAB 144B** – Application for Additional Clinical Laboratory Testing Sites, **ONLY** if qualified for multiple site exception under California Business and Professions Code 1265 (d).
- **LAB 1513** - Disclosure of Ownership and Control Interest Statement, including home addresses of all owners and corporate officers
- **LAB 116** – Laboratory Personnel Report
- **LAB 144A** – Laboratory Testing Declaration, including name(s) of manufacturer(s) and/or equipment(s) and annual volumes
- **LAB 183** - Director's Attestation (each director or co-director must file separate attestation)

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Federal forms to complete:

- **CMS 116** – CLIA application, unless already certified by CMS.
- **CMS 209** – Laboratory Personnel Report (CLIA)
- **Form 1513** – Disclosure of Ownership and Control Interest Statement for CLIA purposes. Obtain a copy from the LFS Laboratory Licensing website:
<http://www.dhs.ca.gov/ps/ls/LFSB/html/lablic.htm>. Do not use CMS 1513 that is available on the CMS website.

Other requirements:

- Articles of incorporation which include all owners' name(s), a corporation or partnership agreement, if applicable. Include a separate sheet with the name or address(es) of board members.
- Original signatures must be on all forms where signatures are required.
- Note: A laboratory director may direct no more than three (3) laboratories in any combination of waived, PPMP, moderate or high complexity. (Title 17, California Code of Regulations, Section 1050 (c)(8).)

State LAB forms can be downloaded from <http://www.dhs.ca.gov/publications/forms/labs.htm>.
Federal forms (CMS 116 and 209) can be downloaded from <http://www.cms.hhs.gov/forms/>.
Form 1513 can be downloaded from <http://www.dhs.ca.gov/ps/ls/LFSB/html/lablic.htm>.

Submit fee and all required documents to LFS at:

DHS- Laboratory Field Services Branch
850 Marina Bay Parkway, Bldg P, 1st Floor
Richmond, CA 94804-6403

Note that no clinical laboratory license shall be issued by the department unless the clinical laboratory is found to be in compliance with applicable state laws and regulations.